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September 7, 2011

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2011 SEP 12 AM 11:32Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a Maternal Toxicity Study in New Zealand White Rabbits, (Range Finding) with [REDACTED]

Dear Sir/Madam:

[REDACTED] is submitting results of a Maternal Toxicity Study in New Zealand White Rabbits, (Range Finding) with [REDACTED], conducted by [REDACTED]. The substance is a developmental pesticide.

The test substance was administered to groups of 10 pregnant New Zealand White Rabbits via gavage from gestational day (GD) 6 through GD 28. All surviving animals were sacrificed on GD 29 and examined.

Following dose levels had been investigated:

- 250, 500 and 1000 mg/kg bw/d

The following findings were observed (in comparison to control):

1000 mg/kg bw/d

- Three of ten animals with abort between GD 27 and 29
- Reduced food consumption between GD 13 and 28 (down to 40%)
- Reduced net weight change from day 6 (-514g vs. -109g in control)
- Reduced carcass weight (89%)

500 and 250 mg/kg bw/d

- No treatment-related adverse findings



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[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures

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September 7, 2011

RECEIVED
OPPT CBIC
2011 SEP 12 AM 11:34

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of an Enhanced One-Generation Reproduction Toxicity Study in Wistar Rats with [REDACTED]

Dear Sir/Madam:

[REDACTED] is submitting results of an Enhanced One-Generation Reproduction Toxicity Study (Rangefinding) in Wistar Rats [CrI:WI(HAN) Charles River, Sulzfeld, Germany], with reference to OECD Guidelines 415/416, with [REDACTED], conducted by [REDACTED]. The substance is an experimental pesticide.

The test substance is administered to groups of 10 male and 10 female young Wistar rats (F0 parental generation) via the diet. The concentration levels are 0, 300, 650, 1250 and 2500 ppm. About 6 weeks after the beginning of treatment, F0 animals will be mated to produce a litter (F1). Mating pairs are from the same dose group. Pregnant females will be allowed to give birth and the offspring is brought up until postnatal day (PND) 21 or, for selected animals until sexual maturity. The study is terminated with the sacrifice of the F0 and F1 animals, necropsy and histopathology in selected organs.

After the first treatment week, the high-dose parental animals (2500 ppm) showed markedly decreased food consumption (more than 50%), stagnant body weight gain (males) or body weight loss (females) and multitude adverse clinical symptoms, such as poor general and nutritional state, piloerection and high-stepping gait. After the death of 3 females, which preterminally exhibited apathia, tremors and lateral position, the remaining animals of the group were humanely killed.

The other dose groups were unaffected.

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